

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5**

**IN THE MATTER OF:**

**Kremers Urban Pharmaceuticals Inc.  
A Lannett Company Subsidiary  
1001 C Avenue West  
Seymour, Indiana, 47274**

**ATTENTION:**

**Sophia Wright  
Environmental Health & Safety Manager**

**Request to Provide Information Pursuant to the Clean Air Act**

The U.S. Environmental Protection Agency is requiring Kremers Urban Pharmaceuticals Inc., (Kremers or you) to submit certain information about the facility at 1001 C Avenue West, Seymour, Indiana. Appendix A provides the instructions needed to answer this information request, including instructions for electronic submissions. Appendix B specifies the information that you must submit. You must send this information to us within seven (7) calendar days after you receive this request.

We are issuing this information request under Section 114(a) of the Clean Air Act (the CAA), 42 U.S.C. § 7414(a). Section 114(a) authorizes the Administrator of EPA to require the submission of information. The Administrator has delegated this authority to the Director of the Air and Radiation Division, Region 5.

Kremers owns and operates an emission source at the Seymour, Indiana facility. We are requesting this information to determine whether your emission source is complying with the Indiana State Implementation Plan and applicable federal regulations.

Kremers must send all required information to:

Attn: Compliance Tracker, AE-17J  
Air Enforcement and Compliance Assurance Branch  
U.S. Environmental Protection Agency  
Region 5  
77 W. Jackson Boulevard  
Chicago, Illinois 60604

Kremers must submit all required information under an authorized signature with the following certification:

I certify under penalty of law that I have examined and am familiar with the information in the enclosed documents, including all attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are, to the best of my knowledge and belief, true and complete. I am aware that there are significant penalties for knowingly submitting false statements and information, including the possibility of fines or imprisonment pursuant to Section 113(c)(2) of the Clean Air Act and 18 U.S.C. §§ 1001 and 1341.

As explained more fully in Appendix C, you may assert a claim of business confidentiality under 40 C.F.R. Part 2, Subpart B for any part of the information you submit to us. Information subject to a business confidentiality claim is available to the public only to the extent, and by means of the procedures, set forth at 40 C.F.R. Part 2, Subpart B. If you do not assert a business confidentiality claim when you submit the information, EPA may make this information available to the public without further notice. You should be aware, moreover, that pursuant to Section 114(c) of the CAA and 40 C.F.R. § 2.301(a) and (f), emissions data, standards and limitations are not entitled to confidential treatment and shall be made available to the public notwithstanding any assertion of a business confidentiality claim. Appendix C provides additional information regarding the meaning and scope of the term "emissions data."

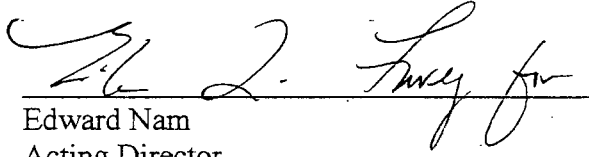
This information request is not subject to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*, because it seeks collection of information from specific individuals or entities as part of an administrative action or investigation.

We may use any information submitted in response to this request in an administrative, civil or criminal action.

Failure to comply fully with this information request may subject Kremers to an enforcement action under Section 113 of the CAA, 42 U.S.C. § 7413.

You should direct any questions about this information request to Albana Bega at (312) 353-4789 or Constantinos Loukeris at (312) 353-6198.

6/8/16  
Date

  
\_\_\_\_\_  
Edward Nam  
Acting Director  
Air and Radiation Division

## **Appendix A**

When providing the information requested in Appendix B, use the following instructions and definitions.

### **Instructions**

1. Provide a separate narrative response to each question and subpart of a question set forth in Appendix B.
2. Precede each answer with the number of the question to which it corresponds and, at the end of each answer, identify the person(s) who provided information used or considered in responding to that question, as well as each person consulted in the preparation of that response.
3. Indicate on each document produced, or in some other reasonable manner, the number of the question to which it corresponds.
4. When a response is provided in the form of a number, specify the units of measure of the number in a precise manner.
5. Where information or documents necessary for a response are neither in your possession nor available to you, indicate in your response why the information or documents are not available or in your possession, and identify any source that either possesses or is likely to possess the documents or information.
6. If information not known or not available to you as of the date of submission later becomes known or available to you, you must supplement your response. Moreover, should you find at any time after the submission of your response that any portion of the submitted information is false or incorrect, you must notify EPA as soon as possible.

### **Electronic Submissions**

To aid in our electronic recordkeeping efforts, we request that you provide all documents responsive to this information request in an electronic format according to paragraphs 1 through 6, below. These submissions are in lieu of hard copy.

1. Provide all responsive documents in Portable Document Format (PDF) or similar format, unless otherwise requested in specific questions. If the PDFs are scanned images, perform at least Optical Character Recognition (OCR) for "image over text" to allow the document to be searchable. Submitters providing secured PDFs should also provide unsecured versions for EPA use in repurposing text.
2. When specific questions request data in electronic spreadsheet form, provide the data and corresponding information in editable Excel format, and not in image format. If Excel format is not available, then the format should allow for data to be used in calculations by a standard spreadsheet program such as Excel.

3. Provide submission on physical media such as compact disk, flash drive or other similar item.
4. Provide a table of contents for each compact disk or flash drive containing electronic documents submitted in response to our request so that each document can be accurately identified in relation to your response to a specific question. *We recommend the use of electronic file folders organized by question number.* In addition, each compact disk or flash drive should be labeled appropriately (e.g., Company Name, Disk 1 of 4 for Information Request Response, Date of Response).
5. Documents claimed as confidential business information (CBI) must be submitted on separate disks/drives apart from the non-confidential information. This will facilitate appropriate records management and appropriate handling and protection of the CBI. Please follow the instructions in Appendix C for designating information as CBI.
6. Certify that the attached files have been scanned for viruses and indicate what program was used.

#### **Definitions**

All terms used in this information request have their ordinary meaning unless such terms are defined in the CAA, 42 U.S.C. §§ 7401 *et seq.*

## **Appendix B**

### **Information You Are Required to Submit to EPA**

Kremers must submit the following information for its facility located at 1001 C Avenue West, Seymour, Indiana (Facility) pursuant to Section 114(a) of the CAA, 42 U.S.C. § 7414(a), within seven (7) calendar days of its receipt of this letter:

1. Provide copies of the 2013, 2014, and 2015 annual air emissions calculations submitted to the Indiana Department of Environmental Management. The response should include but not be limited to the following:
  - a. A Microsoft Excel spreadsheet containing calculations;
  - b. A narrative describing the method used for the annual emissions calculations for each pollutant, including the basis of any emissions factors used; and
  - c. A table describing the assumed/estimated capture efficiencies for each control device(s) and the associated emission unit(s), including any associated documentation (i.e., testing and engineering assessments) used in developing the capture efficiencies.
2. Provide a list of all solvents used at the Facility that contain any amount of volatile organic compound (VOC) or hazardous air pollutant (HAP). The response should include but not be limited to the solvents used in manufacturing, pilot projects, and in the liquid pharmaceuticals process. For each solvent, provide the following:
  - a. The amount of the VOC and/or HAP present (i.e., percent by weight); and
  - b. Annual usage in pounds per year.
3. Provide the date and supporting documentation of when Kremers stopped using denatured ethanol.
4. For the Niferex process, provide the following information:
  - a. Identify each step in the Niferex process;
  - b. Provide the duration of each step (in hours); and
  - c. Provide the number of batches completed for each month at the Facility for the past three years of operation.

5. Identify the full composition of the "Pharmaceutical Glaze" (i.e., state each constituent that makes up the 35-40% of the Pharmaceutical Glaze not listed in the Safety Data Sheet provided to EPA during EPA's February 2 and 3, 2016 inspection). Provide the quantities of Pharmaceutical Glaze used in each batch for each process at the Facility.
6. Provide the amount of methylene chloride used in each batch for each process at the Facility.
7. Provide a copy of the "process vent design emission evaluation" (Engineering Study Report conducted in 2006), which determined that the Facility's process unit exhaust systems contained less than 50 part per million by volume HAP.
8. Provide an explanation, including supporting documentation and data, regarding the determination that "Pharmaceutical Glaze" and "Castor Wax Coating" application equipment are exempt from the leak detection and repair (LDAR) provision of 40 C.F.R. Part 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production), pursuant to § 63.1255(a)(9) of Subpart GGG (i.e., on the basis of operating less than 300 hours per year).
9. Provide a copy of the "LDAR Audit" and supporting documentation and data completed at the Facility referenced by Ms. Wise of Wilcox Environmental Engineering (consultant), during EPA's February 2 and 3, 2016 inspection.
10. Provide an explanation, including supporting documentation and data, to describe why the methylene chloride used in the "Pharmaceutical Glaze" pan coating and drying process was reported pursuant to the 40 C.F.R. Part 63, Subpart GGG, and methylene chloride used in the Niferex process is not reported.
11. State whether the Facility has identified any point of determination (POD) of wastewater as defined at 40 C.F.R. § 63.1251 pursuant to 40 C.F.R. § 63.1256. For each POD, provide the following:
  - a. POD identification;
  - b. Annual average concentration of each partially soluble and/or soluble HAP compounds listed in Table 2 and Table 3 of 40 C.F.R. Part 63, Subpart GGG;
  - c. Flow rates; and
  - d. A diagram indicating the flow of stream(s) with each opening to the atmosphere.
12. Provide copies of the Initial Notification and Notification of Compliance Status submitted pursuant to 40 C.F.R. Part 63, Subpart DDDDD (National Emission Standards for Hazardous Air Pollutants for Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters) for all of the Facility's boilers. State the date each Initial Notification and Notification of Compliance Status was prepared and/or submitted, and identify the agency or agencies to which each certification was submitted.

## **Appendix C**

### **Confidential Business and Personal Privacy Information**

#### **Assertion Requirements**

You may assert a business confidentiality claim covering any parts of the information requested in the attached Appendix B, as provided in 40 C.F.R. § 2.203(b).

Emission data provided under Section 114 of the CAA, 42 U.S.C. § 7414, is not entitled to confidential treatment under 40 C.F.R. Part 2.

“Emission data” means, with reference to any source of emissions of any substance into the air:

Information necessary to determine the identity, amount, frequency, concentration or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source (or of any pollutant resulting from any emission by the source), or any combination of the foregoing;

Information necessary to determine the identity, amount, frequency, concentration or other characteristics (to the extent related to air quality) of the emissions which, under an applicable standard or limitation, the source was authorized to emit (including to the extent necessary for such purposes, a description of the manner and rate of operation of the source); and

A general description of the location and/or nature of the source to the extent necessary to identify the source and to distinguish it from other sources (including, to the extent necessary for such purposes, a description of the device, installation, or operation constituting the source).

40 C.F.R. § 2.301(a)(2)(i)(A), (B) and (C).

To make a confidentiality claim, submit the requested information and indicate that you are making a claim of confidentiality. Any document for which you make a claim of confidentiality should be marked by attaching a cover sheet stamped or typed with a caption or other suitable form of notice to indicate the intent to claim confidentiality. The stamped or typed caption or other suitable form of notice should employ language such as “trade secret” or “proprietary” or “company confidential” and indicate a date, if any, when the information should no longer be treated as confidential. Information covered by such a claim will be disclosed by EPA only to the extent permitted and by means of the procedures set forth at Section 114(c) of the CAA and 40 C.F.R. Part 2. Allegedly confidential portions of otherwise non-confidential documents should be clearly identified. EPA will construe the failure to furnish a confidentiality claim with your response to the information request as a waiver of that claim, and the information may be made available to the public without further notice to you.



### **Determining Whether the Information Is Entitled to Confidential Treatment**

All confidentiality claims are subject to EPA verification and must be made in accordance with 40 C.F.R. § 2.208, which provides in part that you must satisfactorily show: that you have taken reasonable measures to protect the confidentiality of the information and that you intend to continue to do so, that the information is not and has not been reasonably obtainable by legitimate means without your consent and that disclosure of the information is likely to cause substantial harm to your business's competitive position.

Pursuant to 40 C.F.R. Part 2, Subpart B, EPA may at any time send you a letter asking that you support your confidential business information (CBI) claim. If you receive such a letter, you must respond within the number of days specified by EPA. Failure to submit your comments within that time would be regarded as a waiver of your confidentiality claim or claims, and EPA may release the information. If you receive such a letter, EPA will ask you to specify which portions of the information you consider confidential by page, paragraph and sentence. Any information not specifically identified as subject to a confidentiality claim may be disclosed to the requestor without further notice to you. For each item or class of information that you identify as being CBI, EPA will ask that you answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a special event or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
2. Information submitted to EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question number 1?
3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
4. Is the information contained in any publicly available databases, promotional publications, annual reports or articles?—Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
5. Has any governmental body made a determination as to confidentiality of the information? If so, please attach a copy of the determination.
6. For each category of information claimed as confidential, explain with specificity why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as

substantial and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.
8. Is there any other information you deem relevant to EPA's determination regarding your claim of business confidentiality?

If you receive a request for a substantiation letter from the EPA, you bear the burden of substantiating your confidentiality claim. Conclusory allegations will be given little or no weight in the determination. In substantiating your CBI claim(s), you must bracket all text so claimed and mark it "CBI." Information so designated will be disclosed by EPA only to the extent allowed by and by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.

### **Personal Privacy Information**

Please segregate any personnel, medical and similar files from your responses and include that information on a separate sheet(s) marked as "Personal Privacy Information." Disclosure of such information to the general public may constitute an invasion of privacy.

**CERTIFICATE OF MAILING**

I, Loretta Shaffer, certify that I sent a Request to Provide Information Pursuant to the  
Clean Air Act by Certified Mail, Return Receipt Requested, to:

Sophia Wright  
Environmental Health & Safety Manager  
Kremers Urban Pharmaceuticals Inc.  
A Lannett Company Subsidiary  
1001 C Avenue West  
Seymour, Indiana 47274

I also certify that I sent a copy of the Request to Provide Information Pursuant to the  
Clean Air Act by E-mail to:

Phil Perry,  
Chief, Air Compliance Branch  
PPERRY@idem.IN.gov

On the 9<sup>th</sup> day of June 2016.

Kathy Jones  
for Loretta Shaffer, Program Technician  
AECAB, PAS

CERTIFIED MAIL RECEIPT NUMBER: 7011 1150 0000 2640 8749